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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,300	06/21/2007	Eric Thor Fossel	S1509.70037US01	7179

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EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,300	FOSSEL, ERIC THOR	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *5,6,11,13,17 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-10,12,14-16,18-23 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/2009; 10/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/2009 has been entered.

2. Claims 5, 6, 11, 13, 17, and 24-26 are canceled.

3. Claims 1-4, 7-10, 12, 14-16, 18-23, and 27-29 are examined on the merits.

Response to Arguments

4. Applicant's arguments filed 03/13/2009 have been fully considered but they are not persuasive:

With respect to independent claims 1, 18, and 29, Applicant argues that Fossel does not disclose the claimed invention because nowhere does Fossel specifically teach applying L-arginine to the breast. In fact, the word "breast" appears nowhere in Fossel.

However, invention of Fossel is disclosed for applying to the selected area of the skin. The fact that the human breast is covered by the skin is the matter of the Common Knowledge and the number of anatomical sources can be broth as evidence (i.e. anatomical atlases) by the Applicant's request.

5. Applicant further argues that Fossel does not teach that the breast is a selected area of the skin.

However, since the human breast is not the whole human body but the part of it, the skin covering the human breast is a skin covering a part of body that can be selected if required. Therefore the skin covering the human breast can be interpreted as a selected area of the skin.

6. Applicant further argue that Fossel does not disclose the claimed invention because a rejection based on a unsupported supposition that a composition is "capable" of being used in a particular application that is not actually described in the reference does not constitute a proper rejection under § 102(b).

However, as the Federal Circuit has stated, the claimed invention must only be capable of performing some beneficial function. See In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA), reh 'g denied, 480 F.2d 879 (CCPA 1973); In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

7. With respect to dependent claims 2, 4, 10, 16, 20, and 23, Applicant's arguments are substantially identical to arguments discussed above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 7-9, 12, 14, 15, 18, 19, 21, 22, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Fossel (US 2003/0028169).

10. In Re claim 1, Fossel discloses the method comprising an act of:

applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, for a period of time sufficient for treatment fully capable for sagging skin treatment, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

11. In Re claims 3 and 19, Fossel discloses the method wherein the delivery vehicle is a cream (P. 1, [0015], ln. 1-2).

12. In Re claim 7, Fossel discloses the method wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what reads on "at least 5%" as claimed.

13. In Re claims 8 and 21, Fossel discloses the method wherein the delivery vehicle comprises the water or the oil (P. 1, [0015], ln. 7).

14. In Re claims 9 and 22, Fossel discloses the method fully capable to be repeatable (P. 1, [0015], ln. 1-3).

15. In Re claim 12, since Fossel discloses the concentration of nitic oxide donor L-arginine of 12.5% (P. 1, [0015], ln. 3) as claimed, this amount of arginine is fully capable of producing the claimed function, i. e. act for at least about 3 hours, as per claim 12.

16. In Re claim 14, 15, 27, and 28, Fossel discloses the method wherein the ionic salt comprises sodium chloride, magnesium chloride, or choline chloride (P. 1, [0015], ln. 4-7), and their combined amount is 10% as per claims 15 and 28.

17. In Re claim 17, Fossel teaches the presence of hostile environment (Abstract, ln. 4-6).

18. In Re claim 18, Fossel discloses the method comprising an act of:

applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, and fully capable of being applied for a period of time sufficient to allow the breast skin to absorb a sufficient quantity of L-arginine to produce a smoother surface, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

19. In Re claim 29, Fossel discloses the method comprising an act of:

applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, for a period of time sufficient for treatment fully capable for sagging skin treatment, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the

effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims 10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169).

23. In Re claim 10, Fossel discloses the claimed invention discussed above, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin between 2 and 30 times, inclusively, within a time period of about 30 days.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time range and overall duration of treatment, since the overall duration of the medical treatment by local action compositions and the rate of application of said compositions depend of the type of skin disease, degree of the skin lesion, and

degree of the positive reaction of the patient, and therefore is the matter of routine experimentation what lies within the routine skill in the art.

21. In Re claim 23, Fossel discloses the claimed invention discussed above, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin after between about 8 hours and about 48 hours after the act of applying the delivery vehicle.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time repeating range because the treatment time repeating range depends of the skin resistance level, which can vary from patient to patient, and therefore is the matter of optimization.

24. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Nakata et al. (US 5,332,758).

Fossel discloses the claimed invention discussed above, but does not expressly disclose the method wherein the sagging is determined using viscoelasticity.

Nakata teaches that it is known to use Skin Viscoelasticity Test for skin diseases diagnostics (See Col. 17, ln. 9-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossel with the determination of sagging skin, as taught by Nakata, because such modification would provide the most accurate diagnostic of the specific disease prior the therapeutic treatment.

25. Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Cooper (US 6,387,081).

Fossel discloses the claimed invention discussed above, but does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Cooper refers to generally conventional way to apply skin treatment compositions fully capable of being applied to the breast, since the breast is the selected area of the skin, by rubbing-in with the fingers (Col. 1, ln. 32-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossel with the delivering composition into the region of skin by rubbing, as suggested by Cooper, because such modification would simplify the treatment by using well known traditional techniques.

26. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Marty (US 4,702,913).

Fossel discloses the claimed invention discussed above, but does not expressly disclose the method wherein the nitric oxide donor comprises one or more of a polysaccharide-bound'nitric oxide-nucleophile adduct, a N-nitroso-N-substituted hydroxylamines, a compound containing a sulphydryl group and a NO donor group, 1,3- (nitrooxymethy1)phenyl-2-hydroxybenzoate, a gel comprising a nitrite salt and an acid, S- nitrosothiols, a nitrite, a 2-hydroxy-2-nitrosohydrazine, a substrate for nitric oxide synthase, a cytokine, an adenosine, bradykinin, calreticulin, bisacodyl, phenolphthalein, or endothelein.

Marty teaches that it is known to use adenosine in the cosmetic compositions (See Col. 2, ln. 42-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossel with the use of adenosine, as taught by Marty, because such modification would improve cosmetic or/and therapeutic effect, since adenosine promotes the release of the nitric oxide radical.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
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